E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2020-0498; FRL-9521-01-OCSPP]

Glufosinate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of glufosinate in or on multiple commodities that are identified and discussed later in this document. Interregional Project Number 4 (IR-4) and BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2020-0498, is available online at *https://www.regulations.gov* or in-person at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566-1744.

For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Acting Director,

Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (202) 566-1030; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40*.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2020-0498 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before

[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2020-0498, by one of the following methods:

• *Federal eRulemaking Portal*: *https://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of December 21, 2020 (85 FR 82998) (FRL-10016-93), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0E8859) by IR-4, NC State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606. The petition requested that 40 CFR 180.473 be amended to establish tolerances for residues of the herbicide glufosinate-ammonium, determined by measuring the sum of glufosinate-ammonium, butanoic acid, 2-amino-4-(hydroxymethylphosphinyl) monoammonium salt, and its metabolites, 2-(acetylamino)-4-

(hydroxymethyl phosphinyl)butanoic acid, and 3-(hydroxymethylphosphinyl)propanoic acid, expressed as 2-amino-4-(hydroxymethylphosphinyl)butanoic acid equivalents in or on avocado at 0.03 parts per million (ppm); bushberry subgroup 13-07B at 0.15 ppm; cottonseed subgroup 20C at 4 ppm; fig at 0.07 ppm; fig, dried at 0.2 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 0.05 ppm; hop, dried cones at 0.9 ppm; melon subgroup 9A at 0.08 ppm; pepper/eggplant subgroup 8-10B at 0.08 ppm; rapeseed, subgroup 20A at 0.4 ppm; squash/cucumber subgroup 9B at 0.15 ppm; tomato, paste at 0.11 ppm; tomato, subgroup 8-10A at 0.06 ppm; tropical and subtropical, small fruit, edible peel, subgroup 23A at 0.5 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.8 ppm. Upon the establishment of those tolerances, the petition also requested that EPA remove the following tolerances from 40 CFR 180.473: apple at 0.05 ppm; bushberry subgroup 13B at 0.15 ppm; canola, seed at 0.40 ppm; cotton, undelinted seed at 4.0 ppm; grape at 0.05 ppm; juneberry at 0.10 ppm; lingonberry at 0.10 ppm; olive at 0.50 ppm; pistachio at 0.10 ppm; potato at 0.80 ppm; and salal at 0.10 ppm. That document referenced a summary of the petition prepared by IR-4, the petitioner, and is available in the docket, *https://www.regulations.gov*. Two comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

In the *Federal Register* of August 24, 2021 (86 FR 47275) (FRL-8792-02-OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F8865) by BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.473 be amended to establish or revise tolerances for residues of the herbicide glufosinate-ammonium, determined by measuring the sum of glufosinate-ammonium, butanoic acid, 2-amino-4-(hydroxymethylphosphinyl) monoammonium salt, and its metabolites, 2-(acetylamino)-4-(hydroxymethyl phosphinyl)butanoic acid, and 3-(hydroxymethylphosphinyl)propanoic acid, expressed as 2-amino-4-(hydroxymethylphosphinyl)butanoic acid equivalents in or on oilseed, cottonseed subgroup 20C at 15 ppm and cotton gin byproducts at 50 ppm. That document

referenced a summary of the petition prepared by BASF, the registrant, and is available in the docket, *https://www.regulations.gov*. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is establishing some tolerances at different levels than the petitioner requested. The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for glufosinate including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with glufosinate follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also

considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The toxicology database for glufosinate is complete. A primary effect associated with glufosinate is inhibition of glutamine synthetase in the brain, which may be of significant concern for possible neurotoxicity and/or expression of clinical signs. Clinical signs of neurotoxicity were seen in several studies, including the subchronic, developmental, and chronic studies in rats and dogs. In addition to a variety of clinical signs, retinal atrophy was also observed in the subchronic and chronic rat studies. The rat developmental neurotoxicity (DNT) study demonstrated altered brain morphometrics.

There was evidence of both qualitative (rabbit developmental study) and quantitative (rat reproductive toxicity study; DNT study) susceptibility following glufosinate exposure. A 28-day inhalation toxicity study demonstrated toxicity at the lowest dose tested as indicated by lung and bronchial congestion. Glufosinate ammonium is classified as Toxicity Category III or IV for acute oral, dermal, and inhalation toxicity; and is not a dermal or eye irritant, nor a dermal sensitizer. Glufosinate was classified as "not likely to be a human carcinogen." There was no evidence of a treatment-related increase in tumors in either rats or mice.

Specific information on the studies received and the nature of the adverse effects caused by glufosinate as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *https://www.regulations.gov* in the document titled "Glufosinate. Human Health Risk Assessment for the Proposed Use of Glufosinate on tomato subgroup 8-10A; pepper/eggplant subgroup 8-10B; melon subgroup 9A; squash/cucumber subgroup 9B; fig; avocado; hops: and crop group expansions for rapeseed subgroup 20A; cottonseed subgroup 20C; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F; tropical and subtropical, small fruit, edible peel, subgroup 23A; vegetable, tuberous and corm, subgroup 1C; and a crop group conversion for bushberry subgroup 13-07B: an amended application rate for cotton: and revised restricted

entry intervals for cotton, field corn, sweet corn, soybean, and canola" (hereinafter "Glufosinate Human Health Risk Assessment") on pages 43-52 in docket ID number EPA-HQ-OPP-2020-0498.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides*.

A summary of the toxicological endpoints for glufosinate used for human risk assessment can be found in the Glufosinate Human Health Risk Assessment on page 23-26.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to glufosinate, EPA considered exposure under the petitioned-for tolerances as well as all existing glufosinate tolerances in 40 CFR 180.473. EPA assessed dietary exposures from glufosinate in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for glufosinate.

In conducting the acute dietary exposure assessment, EPA used the 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). The acute dietary exposure assessment is unrefined, assuming tolerance level residues and 100% crop treated (100 PCT) for all crop and livestock commodities.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment, EPA used the 2003-2008 food consumption data from the NHANES/WWEIA. EPA used anticipated residues based on average field trial residue levels for plant raw agricultural commodities, PCT information where available, and experimentally-determined processing factors where available. Anticipated residues for livestock commodities were also calculated and incorporated into the assessment.

iii. *Cancer*. EPA has concluded that glufosinate does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

• Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.

• Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.

• Condition c: Data are available on pesticide use and food consumption in a particular area, and the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

For the chronic dietary assessment, the following PCT assumptions were made: almonds: 25%; apples: 5%; apricots: 15%; blueberries: 20%; canola: 55%; cherries: 5%; corn: 2.5%; cotton: 20%; grapes: 20%; hazelnuts: 40%; peaches:10%; pears: 10%; pecans: 1%; pistachios: 35%; plums/prunes: 15%; potatoes: 15%; rice: 1%; soybeans: 10%; sweet corn: 1%; and walnuts: 20%. In the acute analysis, the Agency made the conservative assumption of 100 PCT.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5%. In those cases, the Agency would use less than 1% or less than 2.5% as the average PCT value,

respectively. The maximum PCT figure is the highest observed maximum value reported within the recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5% except where the maximum PCT is less than 2.5%, in which case, the Agency uses less than 2.5% as the maximum PCT.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which glufosinate may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for glufosinate in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of glufosinate. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment*.

Based on the Pesticides in Water Calculator (PWC; version 1.52), the estimated drinking water concentrations (EDWCs) of glufosinate are estimated to be 201 ppb for acute dietary exposures and 24.4 ppb parts per billion (ppb) for chronic dietary exposures. Surface water

simulations resulted in the highest EDWCs.

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Glufosinate is currently registered for uses that could result in residential handler and post-application exposures including use on lawn and turf as well as recreational sites such as golf courses. The current action does not add any new uses with residential exposures.

For assessing aggregate exposure to adults, the Agency used exposures from the dermal exposure scenario from high contact lawn activity on treated lawns and turf. For assessing aggregate exposure to children 1 to less than 2 years old, the conservative exposure assessment for dermal plus incidental oral (hand-to-mouth and object-to-mouth) exposure from high contact lawn activity on lawns and turf treated with glufosinate was assumed. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide*.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to glufosinate and any other substances, and glufosinate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that glufosinate has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a

common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data are available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. Quantitative susceptibility was seen in the rat developmental neurotoxicity (DNT) study for glufosinate which demonstrated alterations in brain morphometrics in the adult offspring exposed *in utero* and/or during lactation at dose levels not associated with maternal toxicity. The reproductive toxicity study in rats also showed evidence of quantitative susceptibility indicated by an increase in pup mortality in the absence of parental toxicity. In rabbits, decreased fetal body weight and increased mortality were observed. Since increased fetal mortality was observed in the presence of less severe maternal toxicity (decreased food consumption, body weight, and body weight gain), there is evidence of qualitative susceptibility in the fetuses. The developmental toxicity study in the rat revealed dilated renal pelvis and/or hydroureter in the fetuses at the same dose level that produced significant increases in hyperactivity and vaginal bleeding in the dams indicating no qualitative or quantitative sensitivity.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X for acute dietary

exposure. For all other exposure scenarios where the DNT study or the 28-day inhalation study is used as an endpoint for risk assessment (i.e., short-term incidental oral, short- and intermediate-term dermal, and chronic dietary), EPA is retaining a 10X FQPA SF as a LOAEL to NOAEL extrapolation factor since NOAELs were not observed in those studies. The decision to reduce the FQPA SF to 1X for acute dietary exposure is based on the following findings:

i. The toxicity database for glufosinate is complete.

ii. A number of clinical signs indicative of neurotoxicity were noted in rat and dog studies. A critical indication of neurotoxicity was also evident in the DNT study where alterations in brain morphometrics in the adult offspring were demonstrated. However, concern is low since the selected points of departure are protective of observed neurotoxic effects.

iii. Quantitative evidence of increased *in utero* and post-natal susceptibility was identified in rats. However, concern for the observed susceptibility is low as all selected endpoints are protective of these effects.

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary food exposure assessment was performed based on 100 PCT and tolerance-level residues for all crops and livestock commodities. With limited monitoring data available, upper-bound assumptions were used to determine exposure through drinking water sources. These assessments will not underestimate the exposure and risks posed by glufosinate.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk*. An acute aggregate risk assessment takes into account acute exposure

estimates from dietary consumption of food and drinking water. Using the exposure assumptions described in this unit for acute exposure, EPA has concluded that acute exposure to glufosinate from food and water will utilize 27% of the aPAD with the females 13 to 49 years old population subgroup, the only population group of concern because no appropriate toxicological effect attributable to a single dose was observed for the general U.S. population or any other population subgroup.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to glufosinate from food and water will utilize 37% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Chronic residential exposure to residues of glufosinate is not expected.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Glufosinate is registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to glufosinate.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in a short-term aggregate MOE 5,100 for adults. Likewise, for children 1 to less than 2 years old, the short-term aggregate risk estimates are not of concern. The short-term aggregate MOE is 1,100 and the Agency's level of concern is 1,000 for the particular exposures discussed in this section. Because EPA's level of concern for glufosinate is 1,000 or below, these risks are not of concern.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, glufosinate is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential

exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately-protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for glufosinate.

5. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, glufosinate is not expected to pose a cancer risk to humans.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to glufosinate residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Two analytical methods have been validated by EPA for enforcement of the currently established tolerances: (1) Method HRAV-5A for the determination of glufosinate and glufosinate propanoic acid in/on almond, apple, corn forage, corn grain, grape, and soybean seed; and, (2) Method BK/01/99 used for the determination of glufosinate, N-acetyl-glufosinate, and glufosinate propanoic acid in/on canola seed and sugar beet root.

Based on the results of the crop field trials validating a method similar to Method BK/01/99, EPA concludes that Method BK/01/99 is a suitable method for enforcement of tolerances on avocado, fig, hops, melon, pepper, squash/cucumber and tomato.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section

408(b)(4). EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Codex has not established MRLs for glufosinate in/on cotton, gin byproducts; fig, dried; hop, dried cones; melon, subgroup 9A; pepper/eggplant 8-10B; squash/cucumber subgroup 9B; or tomato, paste.

The U.S. tolerances for avocado and fig are harmonized with the Codex MRLs of 0.1 ppm for avocado and 0.1 ppm for fig. The U.S. tolerance for tomato subgroup 8-10A is harmonized with Codex MRLs of 0.1 ppm on naranjilla and tree tomato.

Tolerances for bushberry subgroup 13-07B; tropical and subtropical, small fruit, edible peel, subgroup 23A; vegetable, tuberous and corm, subgroup 1C; and cottonseed subgroup 20C are not harmonized with the corresponding Codex MRLs because the residue data based on approved application rates indicates that residues of glufosinate would be higher than the Codex MRL. Decreasing the U.S. tolerances would put U.S. growers at risk of having violative residues despite legal use of glufosinate according to the label. The tolerance for rapeseed subgroup 20A at 0.4 ppm is not harmonized with the Codex MRL on rapeseed at 1.5 ppm because the Codex MRL is based on an obsolete use and because available data indicate that 0.4 ppm is sufficient for glufosinate residues from use on rapeseed subgroup 20A. EPA is not harmonizing the U.S. tolerance for fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 0.05 ppm with the Codex MRLs of 0.15 ppm for table and wine grape because the Codex MRLs are based on obsolete data and there are no registered uses in the European Union.

C. Response to Comments

The same two comments were received to both the registrant's and IR-4's notice of filing. Both comments stated in part that the Agency should "deny this profiteering exemption for rutgers." Although the Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops, the existing legal framework provided by section 408 of the FFDCA authorizes EPA to establish tolerances when it determines that the tolerances are

safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that the glufosinate tolerances are safe. The commenter has provided no information indicating that a safety determination cannot be supported.

D. Revisions to Petitioned-for Tolerances

EPA is establishing the tolerances for avocado, fig, and tomato subgroup 8-10A at different levels than requested to harmonize with the Codex MRL.

For cottonseed, subgroup 20C, IR-4 requested a tolerance of 4 ppm based on the existing tolerance of 4 ppm on cotton, undelinted seed; however, BASF also petitioned for a new tolerance on cottonseed subgroup 20C at 15 ppm. EPA is establishing the tolerance at 15 ppm based on the new cotton field trial data. For cotton, gin byproducts, the already established tolerance of 15 ppm is being changed to 30 ppm rather than 50 ppm requested by BASF based on the new field trial data provided for cotton gin byproducts. The tolerance of 30 ppm for cotton gin byproducts is based on the field trials most reflective of the label use pattern on cotton (2 applications of ~0.8 lb ai/A), rather than using field trials that exceed the maximum single application rate.

IR-4 requested a tolerance of 0.2 ppm for fig, dried. EPA is establishing the tolerance for fig, dried at 0.15 ppm to reflect the correct theoretical processing factor. The tolerance level for fig, dried was derived using the combined glufosinate, 3-(hydroxymethylphosphinyl) propanoic acid (MPP), and 2-(acetylamino)-4-(hydroxymethyl phosphinyl) butanoic acid (NAG) highest average field trials (HAFTs) of the fig field trials in combination with the theoretical processing factor of 3.5X rather than 4.8X.

EPA is establishing the tolerance for pepper/eggplant subgroup 8-10B at 0.15 ppm rather than at 0.08 ppm as requested by IR-4. As the representative crops for the subgroup, the field trial data for bell and nonbell peppers were analyzed separately, which resulted in a higher tolerance of 0.15 ppm for nonbell pepper. EPA is using that value to establish the tolerance for

the subgroup.

IR-4 requested a tolerance of 0.11 ppm for tomato, paste but EPA is establishing the tolerance at 0.15 ppm. The tolerance level of 0.15 ppm was derived using the glufosinate and 3-(hydroxymethylphosphinyl) propanoic acid HAFTs from the tomato field trials in combination with the empirically-determined processing factors for glufosinate and 3-(hydroxymethylphosphinyl) propanoic acid.

V. Conclusion

Therefore, tolerances are established for residues of glufosinate, including its metabolites and degradates, in or on avocado at 0.1 ppm; bushberry subgroup 13-07B at 0.15 ppm; cottonseed subgroup 20C at 15 ppm; fig at 0.1 ppm; fig, dried at 0.15 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 0.05 ppm; hop, dried cones at 0.9 ppm; melon subgroup 9A at 0.08 ppm; pepper/eggplant subgroup 8-10B at 0.15 ppm; rapeseed subgroup 20A at 0.4 ppm; squash/cucumber subgroup 9B at 0.15 ppm; tomato, paste at 0.15 ppm; tomato subgroup 8-10A at 0.1 ppm; tropical and subtropical, small fruit, edible peel, subgroup 23A at 0.5 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.8 ppm. EPA is also revising the tolerance for cotton, gin byproducts from 15 ppm to 30 ppm.

Tolerances are also removed for the following commodities due to the establishment of tolerances for the above commodities or previously established tolerances: apple at 0.05 ppm; bushberry subgroup 13B at 0.15 ppm; canola, seed at 0.40 ppm; cotton, undelinted seed at 4.0 ppm; grape at 0.05 ppm; juneberry at 0.10 ppm; lingonberry at 0.10 ppm; olive at 0.50 ppm; pistachio at 0.10 ppm; potato at 0.80 ppm; and salal at 0.10 ppm.

Finally, EPA is revising the title of § 180.473 from “Glufosinate Ammonium; tolerances for residues” to “Glufosinate; tolerances for residues” and revising the tolerance expression for glufosinate in 40 CFR 180.473(a) and (d) to clarify that the tolerance for the active ingredient will be referred to as glufosinate (*i.e.*, the racemic mixture). Glufosinate is a racemic mixture of the D- and L-enantiomers; with the L-enantiomer being responsible for its herbicidal activity.

Glufosinate can exist in multiple forms, including the acid, ammonium, and sodium forms; other salt forms of glufosinate may be possible as well. While there are presently only registrations for the ammonium form of glufosinate, future registration requests may be submitted for the acid, sodium, or other forms. This change to the tolerance expression will cover the particular form (*e.g.*, acid or ammonium) that may be in any particular pesticide product in the future. EPA has determined that it is reasonable to make this change final without prior proposal and opportunity for comment, because public comment is not necessary, in that the change has no substantive effect on the tolerance because ammonium is the only form currently registered.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers,

not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq*.), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 15, 2022.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Amend § 180.473 by:

a. Revising the section heading.

b. In paragraph (a):

i. Revising the introductory text.

ii. Adding a table heading;

iii. Removing the entry for "Apple";

iv. Adding in alphabetical order the entry "Avocado";

v. Removing the entry for "Bushberry subgroup 13B";

vi. Adding in alphabetical order the entry "Bushberry subgroup 13-07B";

vii. Removing the entry for "Canola, seed";

viii. Revising the entry for "Cotton, gin byproducts";

ix. Removing the entry for "Cotton, undelinted seed";

x. Adding in alphabetical order the entries "Cottonseed subgroup 20C"; "Fig"; "Fig, dried"; and "Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F";

xi. Removing the entry for "Grape";

xii. Adding in alphabetical order the entry "Hop, dried cones";

xiii. Removing the entries for "Juneberry" and "Lingonberry";

xiv. Adding in alphabetical order the entry "Melon subgroup 9A";

xv. Removing the entry for "Olive";

xvi. Adding in alphabetical order the entry "Pepper/eggplant subgroup 8-10B";

xvii. Removing the entries for “Pistachio” and “Potato”;

xviii. Adding in alphabetical order the entry “Rapeseed subgroup 20A”;

xix. Removing the entry for “Salal”; and

xx. Adding in alphabetical order the entries “Squash/cucumber subgroup 9B”; “Tomato, paste”; “Tomato subgroup 8-10A”; “Tropical and subtropical, small fruit, edible peel, subgroup 23A”; and “Vegetable, tuberous and corm, subgroup 1C”.

c. In paragraph (d):

i. Revising the introductory text; and

ii. Adding a table heading.

The additions and revisions read as follows:

§ 180.473 Glufosinate; tolerances for residues.

(a) *General*. Tolerances are established for residues of glufosinate, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring the sum of glufosinate (2-amino-4-(hydroxymethylphosphinyl)butanoic acid) and its metabolites, 2-(acetylamino)-4-(hydroxymethyl phosphinyl) butanoic acid, and 3-(hydroxymethylphosphinyl) propanoic acid, expressed as 2-amino-4-(hydroxymethylphosphinyl)butanoic acid equivalents.

Table 1 to Paragraph (a)

Commodity	**Parts per million**
* * * * * * *	
Avocado	0.1
* * * * * * *	
Bushberry subgroup 13-07B	0.15
* * * * * * *	
Cotton, gin byproducts	30
Cottonseed subgroup 20C	15
* * * * * * *	
Fig	0.1
Fig, dried	0.15
* * * * * * *	
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F	0.05
* * * * * * *	
Hop, dried cones	0.9

* * * * * * *	
Melon subgroup 9A	0.08
* * * * * * *	
Pepper/eggplant subgroup 8-10B	0.15
* * * * * * *	
Rapeseed subgroup 20A	0.4
* * * * * * *	
Squash/cucumber subgroup 9B	0.15
Tomato, paste	0.15
Tomato subgroup 8-10A	0.1
Tropical and subtropical, small fruit, edible peel, subgroup 23A	0.5
Vegetable, tuberous and corm, subgroup 1C	0.8

* * * * *

(d) *Indirect or inadvertent residues*. Tolerances are established for indirect or inadvertent residues of glufosinate, including its metabolites and degradates, in or on the commodities in the following table, as a result of the application of glufosinate to crops listed in paragraph (a) of this section. Compliance with the tolerance levels specified in the following table is to be determined by measuring the sum of glufosinate (2-amino-4-(hydroxymethylphosphinyl) butanoic acid) and its metabolite, 3-(hydroxymethylphosphinyl) propanoic acid, expressed as 2-amino-4-(hydroxymethylphosphinyl)butanoic acid equivalents.

Table 2 to Paragraph (d)

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